



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Proposed collection; 60-day comment request**

#### **The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease Among Men and Women in Agriculture (NIEHS)**

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

TO SUBMIT COMMENTS AND FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dale Sandler, Ph.D., Chief, Epidemiology Branch, National Institute of Environmental Health Sciences, NIH, 111 T.W. Alexander Drive, PO Box 12233, MD A3-05, Research Triangle Park, NC 27709, or call non-toll-free number 919-541-4668, or e-mail your request, including your address to: [sandler@niehs.nih.gov](mailto:sandler@niehs.nih.gov). Formal requests for additional plans and instruments must be requested in writing.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

PROPOSED COLLECTION: The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease Among Men and Women in Agriculture, 0925-0406 (Expiration Date 9/30/2016, REVISION), National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

Need and Use of Information Collection:

The purpose of this information collection is to request new components as part of the ongoing Study of Biomarkers of Exposures and Effects in Agriculture (BEEA), as well as continue and complete phase IV (2013-2016) of the Agricultural Health Study (AHS) and continue buccal cell collection. Phase IV will continue to update the occupational and environmental exposure information as well as medical history

information for licensed pesticide applicators and their spouses enrolled in the AHS. The new BEEA components are a control respondent group, and a smartphone application (app), along with new sample collection (buccal cell and air monitoring samples). The new components will use similar procedures to ones already employed on the BEEA study, as well as other NCI studies. The primary objectives of the study are to determine the health effects resulting from occupational and environmental exposures in the agricultural environment. Secondary objectives include evaluating biological markers that may be associated with agricultural exposures and risk of certain types of cancer. Phase IV questionnaire data are collected by using self-administered computer assisted web survey (CAWI); self-administered paper-and-pen (Paper/pen); or an interviewer administered computer assisted telephone interview (CATI) and in-person interview (CAPI) systems for telephone screeners and home visit interviews, respectively. Some respondents are also asked to participate in the collection of biospecimens and environmental samples, including blood, urine, buccal cells (loose cells from the respondent's mouth), and vacuum dust. The findings will provide valuable information concerning the potential link between agricultural exposures and cancer and other chronic diseases among Agricultural Health Study cohort members, and this information may be generalized to the entire agricultural community.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Estimated Annual Number of Respondents	Number of Responses per Respondent	Average Time Per Response (in hours)	Total Annual Burden Hours
Private and Commercial Applicators and Spouses	Reminder, Missing, and Damaged Scripts for Buccal Cell	100	1	5/60	8
Private Applicators	BEEA CATI Eligibility Script	480	1	20/60	160
Private Applicators	Mailed Consent, Pre-Visit Show Card, and Paper/Pen Dust Questionnaire	160	1	20/60	53
Private Applicators	BEEA Home Visit CAPI, Blood, Buccal cell, Urine & Dust	160	1	90/60	240
Private Applicators	BEEA Pre-Visit Scripts	20	3	5/60	5
Private Applicators	BEEA Home Visit CAPI, Blood, Buccal cell, Urine, & Dust x 3	20	3	90/60	90
Private Applicators	BEEA Mailed Consents (Home Visit & Farm Visit), Pre-Visit Show Card, and Paper/Pen Dust Questionnaire	16	1	25/60	7
Private Applicators	BEEA Home Visit CAPI, Blood, Urine, Buccal cell & Dust x 2	16	2	90/60	16
Controls	BEEA CATI Control Eligibility Script	215	1	20/60	72
Controls	BEEA Mailed Consent, Pre-Visit Show Card, and Paper/Pen Dust Questionnaire	67	1	20/60	22
Controls	BEEA Control Home Visit CAPI, Blood, Buccal cell, Urine, & Dust	67	1	90/60	101
Private Applicators	‘Life in a Day’ Smartphone Application x 25	100	25	10/60	417
Private Applicators	Paper/pen, CAWI or CATI	13,855	1	25/60	5,773
Spouses	Paper/pen, CAWI or CATI	10,201	1	25/60	4,250
Proxy	Paper/pen, CAWI or CATI (Attachment 26)	635	1	15/60	159
Total		25,486	28,608		11,516

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 11,516.

Dated: November 20, 2015.

**Chris Long,**

*Acting Executive Officer,*

*NIEHS.*

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